**EXHIBIT 300**                    **CAPITAL ASSET PLAN AND BUSINESS CASE SUMMARY**

# Exhibit 300: Capital Asset Plan and Business Case Summary
## Part I: Summary Information And Justification (All Capital Assets)

**Section A: Overview (All Capital Assets)**

1. **Date of Submission:** 2010-03-17 14:13:49

2. **Agency:** 009

3. **Bureau:** 10

4. **Name of this Investment:** FDA Regulatory Business Information Services

5. **Unique Project (Investment) Identifier:** 009-10-01-03-01-8033-00

6. **What kind of investment will this be in FY 2011?:** Mixed Life Cycle
   - Planning
   - Full Acquisition
   - Operations and Maintenance
   - Mixed Life Cycle
   - Multi-Agency Collaboration

7. **What was the first budget year this investment was submitted to OMB?** *

8. **Provide a brief summary and justification for this investment, including a brief description of how this closes in part or in whole an identified agency performance gap; this description may include links to relevant information which should include relevant GAO reports, and links to relevant findings of independent audits.**

 Regulatory Business Information Services (RBIS) manages ORA's reporting and information management projects. These include: a centralized data warehouse, the Online Reporting, Analysis, and Decision Support System (ORADSS), implemented to provide integrated information for regulatory compliance and risk-based analysis; the Firms Master List Services (FMLS), to manage, improve the quality of, and standardize data on firms; and,the Firms Management Services (FMS) to allow users to easily find and maintain firm data.  ORA and Center staff access these integrated systems for analysis and decision-making used to protect public health and safety and communicate to the public. Over 5,000 users throughout FDA use ORADSS in regulatory compliance and risk-based analysis.  ORADSS uses a commercially available user interface that allows access to standardized reports and simplifies the creation of ad-hoc reports without specialized knowledge of the underlying data. Without ORADSS, only a small group of users were able to access critical data.  ORADSS provides decision support covering all aspects of FDA's mission, from work planning to performance measurement and reporting to Congress.   The FMLS system provides services to manage the demographic data on firms doing business with and/or required to register with the FDA. These tools maintain accurate data in the warehouse and clean up the operational databases.  FMLS standardizes and validates the facility name and address data received from imports, registration and listing systems, and inspections. Much of the data on firms is received from outside the Agency in non-standard and often inaccurate form. Without FMLS, the Agency would be limited in protecting the public by evaluating risks using data on firms in the supply chain.   FMS improves productivity by utilizing modern search technologies and establishing a standard service for adding, modifying, and merging firm data. Enhancements to the RBIS systems, including integration across FDA, provide staff with critical data, improving their ability to make risk-based decisions. Staff will be able to respond more rapidly and effectively to public health crises, such as a salmonella outbreak, to save lives and reduce the cost to industry.
   a. **Provide here the date of any approved rebaselining within the past year, the date for the most recent (or planned)alternatives analysis for this investment, and whether this investment has a risk management plan and risk register.**

**9. Did the Agency's Executive/Investment Committee approve this request?** *
   a. **If "yes," what was the date of this approval?** *

**10. Contact information of Program/Project Manager?**
- **Name:** *
- **Phone Number:** *
- **Email:** *

**11. What project management qualifications does the Project Manager have? (per FAC-P/PM)?** *
- Project manager has been validated according to FAC-PMPM or DAWIA criteria as qualified for this investment.
- Project manager qualifications according to FAC-P/PM or DAWIA criteria is under review for this investment.
- Project manager assigned to investment, but does not meet requirements according to FAC-P/OM or DAWIA criteria.
- Project manager assigned but qualification status review has not yet started.
- No project manager has yet been assigned to this investment.

**12. If this investment is a financial management system, then please fill out the following as reported in the most recent financial systems inventory (FMSI):**

| Financial management system name(s) | System acronym | Unique Project Identifier (UPI) number |
|---|---|---|
| * | * | * |

  a.   **If this investment is a financial management system AND the investment is part of the core financial system then select the primary FFMIA compliance area that this investment addresses (choose only one):** *
- computer system security requirement;
- internal control system requirement;
- core financial system requirement according to FSIO standards;
- Federal accounting standard;
- U.S. Government Standard General Ledger at the Transaction Level;
- this is a core financial system, but does not address a FFMIA compliance area;
- Not a core financial system; does not need to comply with FFMIA

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**Section B: Summary of Funding (Budget Authority for Capital Assets)**

**1.**

| Table 1: SUMMARY OF FUNDING FOR PROJECT PHASES (REPORTED IN MILLIONS) (Estimates for BY+1 and beyond are for planning purposes only and do not represent budget decisions) | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | PY1 and earlier | PY 2009 | CY 2010 | BY 2011 | BY+1 2012 | BY+2 2013 | BY+3 2014 | BY+4 and beyond | Total |
| Planning: | * | * | * | * | * | * | * | * | * |
| Acquisition: | * | * | * | * | * | * | * | * | * |
| Subtotal Planning & Acquisition: | * | * | * | * | * | * | * | * | * |
| Operations & Maintenance: | * | * | * | * | * | * | * | * | * |
| Disposition Costs (optional): | * | * | * | * | * | * | * | * | * |
| SUBTOTAL: | * | * | * | * | * | * | * | * | * |
| **Government FTE Costs should not be included in the amounts provided above.** | | | | | | | | |
| Government FTE Costs | * | * | * | * | * | * | * | * | * |
| Number of FTE represented by Costs: | * | * | * | * | * | * | * | * | * |
| TOTAL(including FTE costs) | * | * | * | * | * | * | * | * | * |

**2. If the summary of funding has changed from the FY 2010 President's Budget request, briefly explain those changes:**
*

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**Section C: Acquisition/Contract Strategy (All Capital Assets)**

**1.**

| Table 1: Contracts/Task Orders Table | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Contract or Task Order Number | Type of Contract/Task Order (In accordance with FAR Part 16) | Has the contract been awarded (Y/N) | If so what is the date of the award? If not, what is the planned award date? | Start date of Contract/Task Order | End date of Contract/Task Order | Total Value of Contract/Task Order (M) | Is this an Interagency Acquisition? (Y/N) | Is it performance based? (Y/N) | Competitively awarded? (Y/N) | What, if any, alternative financing option is being used? (ESPC, UESC, EUL, N/A) | Is EVM in the contract? (Y/N) |
| Various - Contracts Completed in Prior Years | CPFF: Cost Plus Fixed Fee | Y | 2002-01-01 | 2002-01-01 | 2004-08-31 | $6.7 | * | * | * | * | * |
| 263-01-D-0072 | T&M: Time & Materials | Y | 2004-08-12 | 2004-08-12 | 2006-08-11 | $4.0 | * | * | * | * | * |
| HHSF223200650025P | T&M: Time & Materials | Y | 2004-12-22 | 2004-12-22 | 2007-06-21 | $0.5 | * | * | * | * | * |
| HHSF223200650546G | T&M: Time & Materials | Y | 2006-01-06 | 2006-01-06 | 2008-03-31 | $0.5 | * | * | * | * | * |
| HHSF223200650364W | CPFF: Cost Plus Fixed Fee | Y | 2006-04-19 | 2006-04-19 | 2009-04-21 | $5.6 | * | * | * | * | * |
| HHSF223200650363W | CPFF: Cost Plus Fixed Fee | Y | 2006-05-08 | 2006-05-08 | 2009-04-21 | $3.7 | * | * | * | * | * |
| HHSF223200650509W | T&M: Time & Materials | Y | 2006-10-01 | 2006-10-01 | 2007-06-20 | $0.6 | * | * | * | * | * |
| HHSF223200750557G | T&M: Time & Materials | Y | 2007-05-02 | 2007-05-02 | 2008-11-30 | $0.2 | * | * | * | * | * |
| HHSF223200750318P | T&M: Time & Materials | Y | 2007-06-01 | 2007-06-01 | 2009-12-10 | $1.0 | * | * | * | * | * |
| HHSN263999900046I | T&M: Time & Materials | Y | 2007-09-21 | 2007-09-21 | 2010-09-20 | $3.3 | * | * | * | * | * |
| HHSF223200750421W | T&M: Time & Materials | Y | 2007-09-21 | 2007-09-21 | 2010-09-20 | $6.7 | * | * | * | * | * |
| HHSF223200850768G (Purchase DataFlux Software) | FFP: Firm Fixed Price | Y | 2008-07-14 | 2008-07-14 | 2009-07-13 | $0.5 | * | * | * | * | * |
| HHSF223200820065G | T&M: Time & Materials | Y | 2008-08-28 | 2008-09-22 | 2013-09-21 | $2.2 | * | * | * | * | * |
| HHSF223200850520W | T&M: Time & Materials | Y | 2008-09-01 | 2008-09-01 | 2012-08-31 | $3.9 | * | * | * | * | * |
| HHS223200950047G | FFP: Firm Fixed Price | Y | 2009-05-29 | 2009-07-15 | 2010-07-14 | $0.2 | * | * | * | * | * |
| HHSF223200950012T | T&M: Time & Materials | Y | 2009-09-15 | 2009-09-21 | 2010-09-20 | $1.9 | * | * | * | * | * |

**2. If earned value is not required or will not be a contract requirement for any of the contracts or task orders above, explain why:**
*

**3. Is there an acquisition plan which reflects the requirements of FAR Subpart 7.1 and has been approved in accordance with agency requirements?** *
   a. **If "yes," what is the date?** *

| Section D: Performance Information (All Capital Assets) |
|---|

**Table 1: Performance Information Table**

| 2005 | S.O. 2.2 - Protect the public against injuries and environmental threats | * | * | response time to validate that manufacturer data identified in prior notice submittals is consistent with ffrm data, as required by the prior notice interim final rule | two independent databases with no linkage and no real-time ability to verify manufacturer's data. | link that allows validation and reconciliation of data from pn submissions against registration, with response to user within 3 seconds (pnsi) and without delaying response > 5 sec for acs submittals. | system is in production and functioning within these specifications. load testing completed with response 99% of new ffrm records | batch proces for validation in production f ffrm and oasis real time validation is i production fo pnsi. all (100% ffrm records a validated by fmls. |
|---|---|---|---|---|---|---|---|---|
| 2006 | S.O. 2.2 - Protect the public against injuries and environmental threats | * | * | number of pn reports available. | reporting dependent on time-consuming sql queries and manipulation of data in excel; no standard reports available. | expanded range of pn reports allow users to rapidly obtain critical information; 2 initial reports and pn datamart available. | pn data mart and 3 reports are now available using production system. ~10 additional relevant reports available through imports menu | |
| 2006 | Effective Management of Human Capital/Informati on Technology/Res ources | * | * | number of modules/reports with olap capabilities enabled | reporting requires custom development of sql code | 5 modules/ >50 reports | new system is available for target program areas & reports | |
| 2006 | S.O. 2.2 - Protect the public against injuries and environmental threats | * | * | number of canned reports available to allow easy retrieval of data | data resides in database designed for operations, not queries. all reports require custom coding. | organize facts \\ oasis data into pre summarized, aggregated subject area data marts, with at least 200 reports available. | initial oasis data marts are complete. >500 domestic reports are available. | |
| 2006 | S.O. 2.2 - Protect the public against injuries and environmental threats | * | * | interface with new marcs database. measure length of time for extraction job. | data extracted from legacy databases; time will be remeasured just prior to migration. | migration from new system with no significant impact on system performance | marcs plans to move to unix prior to database redesign; work will proceed once marcs is ready. | |
| 2007 | S.O. 2.2 - Protect the public against injuries and environmental threats | * | * | number of data marts available for user queries. | data resides in legacy database designed for operations, not queries. | develop and deploy average of 1 new data mart/year, including firms, products, organizations, and program assignments, to ensure consistent | deferred to fy 2008-9 due to changing priorities. firms and laboratory data marts are in development. additional data marts will be developed following | |

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**Table 1: Performance Information Table**

| | | | | | | reporting across ora enabling broader analysis and trending | completion. |
|---|---|---|---|---|---|---|---|
| 2007 | Effective Management of Human Capital/Information Technology/Resources | * | * | number of separate user accounts required for ora systems | system-specific independent login requires separate account for each system | one user id and password allows user access to all rbis systems along with other ora systems. | single sign-on implemented 6/06. users now login to fda network and have full access to oradss without additional login. |
| 2007 | S.O. 2.2 - Protect the public against injuries and environmental threats | * | * | number of oradss system users | oradss current number of users 100 | oradss will allow additional users to access data from multiple data sources in a timely fashion; expected number of users is 400. | measure successfully completed. over 4000 users have logged into oradss |
| 2007 | Effective Management of Human Capital/Information Technology/Resources | * | * | number of versions of business objects in use in agency | initial deployment is independent, with an older version of business objects. | integrate oradss business objects user interface with fda consolidated architecture to reduce hardware cost and maintenance, so only one version is in use. | oradss has migrated to agency standard version of business objects and meets architecture standards. |
| 2008 | S.O. 2.2 - Protect the public against injuries and environmental threats | * | * | time required to locate (map) domestic firms of interest | 10 min | | |

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**Table 1: Performance Information Table**

## Part II: Planning, Acquisition And Performance Information

**Section A: Cost and Schedule Performance (All Capital Assets)**

### 1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline

| Description of Milestones | Planned Cost ($M) | Actual Cost ($M) | Planned Start Date | Actual Start Date | Planned Completion Date | Actual Completion Date | Planned Percent Complete | Actual Percent Complete |
|---|---|---|---|---|---|---|---|---|
| Program Management - Old Contracts (FDA FTEs, contractors, program management, project management, EPLC, scheduling, tracking, and planning.) | $1.9 | $2.1 | 2001-10-02 | 2001-10-02 | 2006-09-30 | 2006-09-30 | 100.00% | 100.00% |
| Pre-2004 Planning (Initial work on ORADSS and FMLS) | $4.5 | $4.6 | 2001-10-02 | 2001-10-02 | 2003-09-30 | 2003-09-30 | 100.00% | 100.00% |
| Phase 1 ORADSS/FMLS Development (Development and implementation of initial versions of FMLS and the ORADSS pilot) | $6.8 | $6.4 | 2001-10-02 | 2001-10-02 | 2005-09-30 | 2005-09-30 | 100.00% | 100.00% |
| Phase 2 Warehouse (Completion of the first set of data marts and reports, migration to production environment) | $1.6 | $1.5 | 2004-08-01 | 2004-08-01 | 2006-09-30 | 2006-09-30 | 100.00% | 100.00% |
| Phase 2 FMLS (Upgrades and enhancements to FFRM, PNSI, and OASIS interfaces) | $0.8 | $0.8 | 2004-08-01 | 2004-08-01 | 2006-09-30 | 2006-09-30 | 100.00% | 100.00% |
| Project Management 2006-2009 (FDA FTEs, contractors, | $5.0 | $5.0 | 2006-05-01 | 2006-05-01 | 2009-09-30 | 2009-09-30 | 100.00% | 100.00% |

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| | | | | 1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline | | | | |
|---|---|---|---|---|---|---|---|---|
| Description of Milestones | Planned Cost ($M) | Actual Cost ($M) | Planned Start Date | Actual Start Date | Planned Completion Date | Actual Completion Date | Planned Percent Complete | Actual Percent Complete |
| program | | | | | | | | |
| Project Management 2010-2012 (FDA FTEs, contractors, program management, project management, EPLC, scheduling, tracking, and planning.) | $4.6 | $1.3 | 2009-10-01 | 2009-10-01 | 2012-09-30 | | 30.24% | 29.77% |
| Project Management 2013-2016 (FDA FTEs, contractors, program management, project management, EPLC, scheduling, tracking, and planning.) | * | * | 2012-10-01 | | 2016-09-30 | | 0.00% | 0.00% |
| Business Objects XI Migration | $0.2 | $0.2 | 2006-07-01 | 2006-07-01 | 2007-07-31 | 2007-07-31 | 100.00% | 100.00% |
| Firms and Lab Datamarts Phase 1 (Development and Implementation of Phase 1 for Firms Datamart and Labs Datamart) | $1.5 | $1.4 | 2006-04-01 | 2006-04-01 | 2010-03-31 | 2010-05-07 | 100.00% | 100.00% |
| New and Enhanced ORADSS Reports (Reports to support Import and Domestic Operations, RES, Turbo, Center activities and additional business needs; integrate reports with additional data sources, including Documentum repositories) | $4.3 | $0.6 | 2006-06-01 | 2006-07-01 | 2016-09-30 | | 16.17% | 16.18% |

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| 1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Description of Milestones | Planned Cost ($M) | Actual Cost ($M) | Planned Start Date | Actual Start Date | Planned Completion Date | Actual Completion Date | Planned Percent Complete | Actual Percent Complete |
| Additional Datamarts (Complete Firms and Lab Datamarts, Compliance Datamart, and additional datamarts to support business needs) | $3.9 | $0.2 | 2010-01-01 | 2010-04-26 | 2016-09-30 | | 2.80% | 3.82% |
| ORADSS System Modifications and Upgrades (Configuration, analysis, and testing to support infrastructure and system changes, including ORACLE database, server architecture, and Business Objects reporting software). | $3.1 | $1.0 | 2007-03-01 | 2007-03-01 | 2016-09-30 | | 33.11% | 34.49% |
| Data Mining & Predictive Analysis (Procure, integrate, and implement data mining and predictive analysis tools; develop analyses in conjunction with business users to identify high risk firm, products, etc.) | * | * | 2011-04-01 | | 2016-09-30 | | 0.00% | 0.00% |
| ORADSS Monitoring (Procure and implement or develop Tools and processes to validate DW ETL processes, data, and reporting system usage and performance) | $1.6 | $0.9 | 2008-06-01 | 2008-06-01 | 2016-09-30 | | 56.04% | 54.53% |
| ORADSS Data Services | $1.3 | $0.0 | 2010-04-01 | 2010-05-10 | 2016-09-30 | | 4.55% | 3.17% |

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| Description of Milestones | Planned Cost ($M) | Actual Cost ($M) | Planned Start Date | Actual Start Date | Planned Completion Date | Actual Completion Date | Planned Percent Complete | Actual Percent Complete |
|---|---|---|---|---|---|---|---|---|
| **1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline** | | | | | | | | |
| (Integration and support to additional data sources and initiatives, including Firm Management Services, Harmonized Inventory, and PREDICT) | | | | | | | | |
| Geospatial Data and Mapping (Procure and implement geospatial tools such as Google maps and the data to provide geolocation. Create reports to utilize the data). | $0.9 | $0.5 | 2006-05-01 | 2006-05-01 | 2015-09-30 | | 62.33% | 61.41% |
| FMLS Integration With Center Systems (Interfaces and Services to integrate with Center Registration and Listing Systems, including FFRM, DFRM, DRLS) | $0.9 | $0.8 | 2006-07-01 | 2006-07-01 | 2010-12-31 | 2009-11-30 | 100.00% | 100.00% |
| DataFlux Implementation (Procurement and implementation of data quality tool including validation and improvement of matching and survivorship rules) | $1.7 | $1.8 | 2006-06-01 | 2006-07-01 | 2010-09-30 | 2010-07-30 | 100.00% | 100.00% |
| FMLS - MARCS Interfaces (Development and implementation of batch and real-time interfaces and | $1.0 | $0.1 | 2006-07-01 | 2006-07-01 | 2012-09-30 | | 11.22% | 11.22% |

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| | | | | 1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline | | | | |
|---|---|---|---|---|---|---|---|---|
| Description of Milestones | Planned Cost ($M) | Actual Cost ($M) | Planned Start Date | Actual Start Date | Planned Completion Date | Actual Completion Date | Planned Percent Complete | Actual Percent Complete |
| services utilized by MARCS components) | | | | | | | | |
| FMLS - Enterprise Expansion (Support for Harmonized Inventory and other enterprise initiatives to standardize and clean-up firms, products and other FDA-wide data elements. Outreach and support for clean-up in Center systems) | * | * | 2011-01-01 | | 2014-09-30 | | 0.00% | 0.00% |
| FMLS - Data Cleanup Support | $2.6 | $0.0 | 2010-10-01 | 2010-01-04 | 2013-09-30 | | 0.00% | 0.00% |
| FMLI (Develop and implement Firms Master List Interface to allow CFSAN to manage registration data in FMLS) | $0.2 | $0.3 | 2006-05-01 | 2006-05-01 | 2006-12-31 | 2007-05-31 | 100.00% | 100.00% |
| FMS Development (Develop and Implement services to find, add, update, merge and unmerge firms; integrate services with Agency systems including MARCS) | $4.0 | $2.8 | 2006-09-01 | 2006-10-01 | 2013-03-31 | | 70.89% | 49.75% |
| SERS Data Mart (Plan and implement Documentum repository for SERS) | $0.1 | $0.1 | 2006-10-01 | 2006-10-01 | 2008-11-30 | 2008-11-30 | 100.00% | 100.00% |
| OPAS + FWFPS (Additional | $1.2 | $0.6 | 2008-10-01 | 2008-10-01 | 2014-09-30 | | 48.68% | 48.68% |

| **1. Comparison of Actual Work Completed and Actual Costs to Current Approved Baseline** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Description of Milestones** | **Planned Cost ($M)** | **Actual Cost ($M)** | **Planned Start Date** | **Actual Start Date** | **Planned Completion Date** | **Actual Completion Date** | **Planned Percent Complete** | **Actual Percent Complete** |
| Data Systems: Develop, implement and enhance reporting and decision support systems used for work planning and reporting) | | | | | | | | |
| Steady State 2006 | $2.1 | $2.2 | 2005-10-01 | 2005-10-01 | 2006-09-30 | 2006-09-30 | 100.00% | 100.00% |
| Steady State 2007 | $3.6 | $3.2 | 2006-10-01 | 2006-10-01 | 2007-09-30 | 2007-09-30 | 100.00% | 100.00% |
| Steady State 2008 | $2.4 | $2.8 | 2007-10-01 | 2007-10-01 | 2008-09-30 | 2008-09-30 | 100.00% | 100.00% |
| Steady State 2009 | $2.5 | $2.6 | 2008-10-01 | 2008-10-01 | 2009-09-30 | 2009-09-30 | 100.00% | 100.00% |
| Steady State 2010 | $3.5 | $3.0 | 2009-10-01 | 2009-10-01 | 2010-09-30 | | 84.70% | 67.38% |
| Steady State 2011 | * | * | 2010-10-01 | | 2011-09-30 | | 0.00% | 0.00% |
| Steady State 2012 | * | * | 2011-10-01 | | 2012-09-30 | | 0.00% | 0.00% |
| Steady State 2013 | * | * | 2012-10-01 | | 2013-09-30 | | 0.00% | 0.00% |
| Steady State 2014 | * | * | 2013-10-01 | | 2014-09-30 | | 0.00% | 0.00% |
| Steady State 2015 | * | * | 2014-10-01 | | 2015-09-30 | | 0.00% | 0.00% |
| Steady State 2016 | * | * | 2015-10-01 | | 2016-09-30 | | 0.00% | 0.00% |

* - Indicates data is redacted.